Current Challenges

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3 Challenges / Opportunities to Improve Access

- Obtain additional licensed indications for licensed products
- 2. License products in the U.S. that are already licensed by the EMEA
 - Especially when no virus-inactivated plasma-derived or recombinant alternative exists
- 3. Stimulate new product development



Source: NHF MASAC RBD Task Force

Twin Economic Challenges

- I. Bringing Patients to Market
- **II.** Bringing Products to Market



Bringing Patients to Market

- Outreach & Identification
- Health Care Provider Education
- Laboratory Diagnosis (Training)
- Register
- Data Collection/Analysis
- Develop Case for Support
- Government Purchase / Tender or Reimbursement Coverage



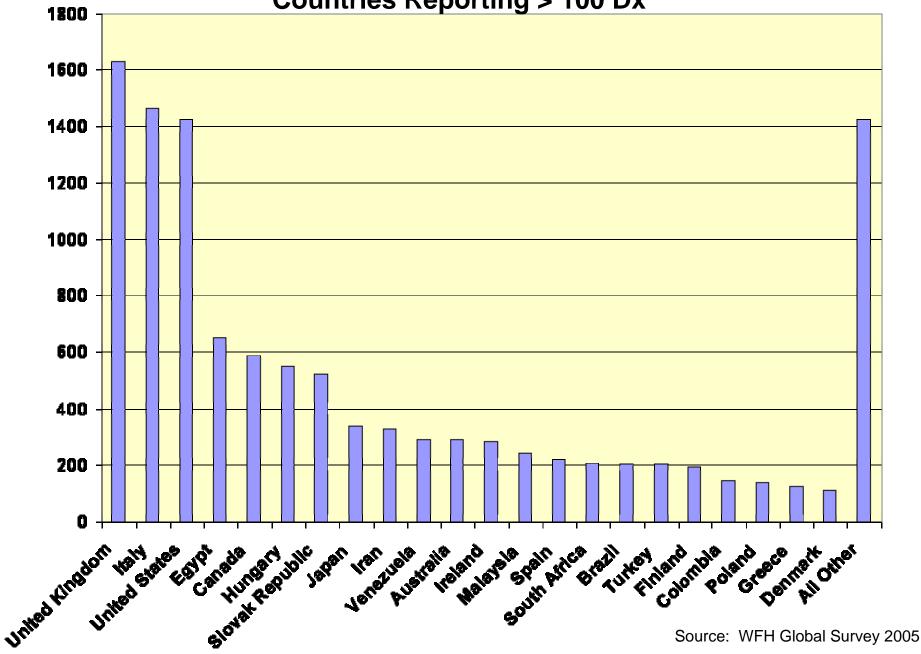
Where are the patients?

WFH 2005 Global Survey

- 96 of 107 member countries reported data
- 61 report Other Hereditary Bleeding Disorders (OHDB) non FVIII, FVIX, VWD
- 78 reporting diagnose with factor assays
- National Data Source for 61 reporting OHDB
 - 16 Survey of HTCs
 - 23 National Registry
 - 12 Other
- 10,496 patients reported with OHDB



Patients with Other Heritable Bleeding Disorders
Countries Reporting > 100 Dx



Bringing Products to Market

"Will health care <u>purchasers</u> agree to buy the product for these needy patients?" – C. Dash

"A 15-fold increase in price would be required to breakeven" - P. Walton

Different economic cosiderations for two market segments?

For-Profit Fractionation Companies

Shareholder Value Public Interest

Non-Profit Fractionation Companies



Questions?



